

Subpart T—Comparison Study for Validating a New Performance-Based Decontamination Solvent Under § 761.79(d)(4)

SOURCE: 63 FR 35473, June 29, 1998, unless otherwise noted.

§ 761.380 Background.

This subpart provides self-implementing criteria for validating the conditions for use in performance-based decontamination of solvents other than those listed in § 761.79(c)(3) and (c)(4). Any person may use this subpart for validating either a chemical formulation or a product with a trade name whether or not the constituents of the product are proprietary.

§ 761.383 Applicability.

Use the self-implementing decontamination procedure only on smooth, non-porous surfaces that were once in contact with liquid PCBs. Decontamination procedures under this subpart shall exactly parallel § 761.79(c)(3) and (c)(4), except that the procedures described in § 761.79(c)(3)(iii) and (c)(3)(iv) and (c)(4)(iii), (c)(4)(iv) and (c)(4)(vii) may be revised to contain parameters validated in accordance with this subpart.

§ 761.386 Required experimental conditions for the validation study and subsequent use during decontamination.

The following experimental conditions apply for any solvent:

(a) *Temperature and pressure.* Conduct the validation study and perform decontamination at room temperature (from ≥ 15 °C to ≤ 30 °C) and at atmospheric pressure.

(b) *Agitation.* Limit the movement in the solvent to the short-term movement from placing the contaminated surface into the soak solvent and from removing the surface from the soak solvent.

(c) *Time of soak.* Soak the surface for a minimum of 1 hour.

(d) *Surface conditions for the validation study.* Prior to beginning the validation study, ensure that there are no free-flowing liquids on surfaces and that surfaces are dry (i.e., there are no liq-

uids visible without magnification). Also ensure that surfaces are virtually free from non-liquid residues, corrosion, and other defects which would prevent the solvent from freely circulating over the surface.

(e) *Confirmatory sampling for the validation study.* Select surface sample locations using representative sampling or a census. Sample a minimum area of 100 cm² on each individual surface in the validation study. Measure surface concentrations using the standard wipe test, as defined in § 761.123, from which a standard wipe sample is generated for chemical analysis. Guidance for wipe sampling appears in the document entitled “Wipe Sampling and Double Wash/Rinse Cleanup as Recommended by the Environmental Protection Agency PCB Spill Cleanup Policy,” available on EPA’s Web site at <http://www.epa.gov/pcb>, or from the Program Management, Communications, and Analysis Office, Office of Resource Conservation and Recovery (5305P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

(f) *Concentration of PCBs.* The method validated may be used only to decontaminate surfaces containing PCBs at concentrations on which the validation study was performed and lower concentrations.

[63 FR 35473, June 29, 1998, as amended at 72 FR 57241, Oct. 9, 2007; 74 FR 30235, June 25, 2009]

§ 761.389 Testing parameter requirements.

There are no restrictions on the variable testing parameters described in this section which may be used in the validation study. The conditions demonstrated in the validation study for these variables shall become the required conditions for decontamination using the solvent being validated and shall replace the comparable conditions in § 761.79(b)(3) through (b)(6). There are limited potential options for varying a single requirement in this section. If you change one of these variable requirements, change it only in the way listed in this section and do not change any other validated conditions. If you desire to change more than one of the requirements in this section, you must conduct a new study

to validate the decontamination under the desired conditions.

(a) The study apparatus is not standardized. Critical components of the study are the PCB material (for example MODEP or some other spiking solution), the volume of the soaking solvent, and the area of the contaminated surface. The EPA study used beakers and shallow dishes as the experimental vessels to contain the surface and solvent during the soaking process. In order to minimize surface-to-volume ratios, it is convenient to utilize flat contaminated surfaces and shallow solvent containers. During the validation study, use the same ratio of contaminated surface area to soak solvent volume as would be used during actual decontamination. It is also permissible to use a smaller surface area to soaking solvent volume than used in the validation study, so long as all other required parameters are used as validated in the confirmation required in § 761.386 (a) through (f), and paragraphs (a) through (c) of this section. Do not use a larger surface-area-to-solvent-volumes ratio or different kind of solvent based on the results of the validation study.

(b) Except for the minimum soak time of 1 hour (as required in § 761.386(c)), the length of soak time is not otherwise restricted in the validation study. The soak time used in the validation study, however, is a use requirement for subsequent decontamination using the solvent being validated. It is permissible to use longer soak times for decontamination than the soak time used in the validation study, if all other parameters required in § 761.386, and paragraphs (a) and (c) of this section are used.

(c) There is no restriction on the kind of material containing PCBs to use to create the surface contamination for the validation study. There is also no restriction on the level of starting PCB surface concentration. It is permissible to use lower concentrations of PCB than the concentration used in the validation study, if all other parameters required in § 761.386 (a) through (f), and paragraphs (a) through (c) of this section are used.

§ 761.392 Preparing validation study samples.

(a)(1) To validate a procedure to decontaminate a surface contaminated with a spill from liquid of a known concentration, contaminate (spike) the surface to be used in the validation study as follows:

(i) Use a spiking solution made of PCBs mixed with a solvent to contaminate clean surfaces. Clean surfaces are surfaces having PCB surface concentrations $<1 \mu\text{g}/100 \text{ cm}^2$ before intentionally contaminating the surface.

(ii) Prior to contaminating a surface for the validation study, mark the surface sampling area to assure that it is completely covered with the spiking solution.

(iii) Deliver the spiking solution onto the surface, covering all of the sampling area. Contain any liquids which spill or flow off the surface. Allow the spiking solution to drip drain off into a container and then evaporate the spiking solution off the contaminated surface prior to beginning the validation study. Contaminate a minimum of eight surfaces for a complete validation study.

(iv) As a quality control step, test at least one contaminated surface to determine the PCB concentration to verify that there are measurable surface levels of PCBs resulting from the contamination before soaking the surface in the decontamination solvent. The surface levels of PCBs on the contaminated surfaces must be $\geq 20 \mu\text{g}/100 \text{ cm}^2$.

(2) To validate a procedure to decontaminate a specified surface concentrations of PCBs as measured by a standard wipe sample, contaminate a minimum of 10 surfaces. Contaminate all the surfaces identically following the procedures in paragraph (a)(1) of this section and measure the PCB surface concentrations of at least three of the surfaces using a standard wipe test to establish a surface concentration to be included in the standard operating procedure. The surface levels of PCBs on the contaminated surfaces must be $\geq 20 \mu\text{g}/100 \text{ cm}^2$.

(b) [Reserved]